In the United States Court of Federal Claims

No. 11-685V
(E-Filed: March 6, 2019)¹

TRYSTAN SANCHEZ, by and through his parents, GERMAIN and JENNIFER SANCHEZ,)

Petitioners,

V.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Vaccine; National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012); Deferential Review of the Special Master's Fact Finding and Weighing of the Evidence.

<u>Lisa A. Roquemore</u>, Rancho Santa Margarita, CA, for petitioners.

<u>Jennifer L. Reynaud</u>, Trial Attorney, with whom were <u>Joseph H. Hunt</u>, Assistant Attorney General, <u>C. Salvatore d'Alessio</u>, Acting Director, <u>Catherine E. Reeves</u>, Deputy Director, <u>Heather L. Pearlman</u>, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

CAMPBELL-SMITH, Judge.

Pursuant to Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims (Appendix B to the Rules of the United States Court of Federal Claims), this opinion was initially filed under seal on February 11, 2019. Pursuant to ¶ 4 of the ordering language, the parties were to propose redactions of the information contained therein on or before February 25, 2019. No proposed redactions were submitted to the court.

On November 8, 2018, petitioners filed a motion for review of the special master's decision of October 9, 2018. See ECF No. 207. Petitioners were granted leave to exceed the page limit for their motion. ECF No. 211 (order). Respondent filed its response brief on December 7, 2018. ECF No. 213. Petitioners were granted leave to file a reply brief not contemplated by this court's rules, ECF No. 215 (order), which was docketed on December 17, 2018, ECF No. 216. Petitioners' request for oral argument, however, is denied because no further development of the parties' arguments is required. Petitioners' motion is fully briefed and ripe for decision.

Like the parties, the court will cite to the special master's entitlement decision as it appears on the docket of this case, ECF No. 205, rather than to the decision available on Westlaw, see Sanchez v. Sec'y of Health & Human Servs., No. 11-685V, 2018 WL 5856556 (Fed. Cl. Spec. Mstr. Oct. 9, 2018). The special master denied petitioners compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (the Vaccine Act). As explained below, the special master's entitlement decision survives this court's review. Accordingly, the court must **DENY** petitioners' motion.

I. Background

As the special master explained in his opinion, in late 2014 Trystan Sanchez was diagnosed as having Leigh's syndrome, a mitochondrial disorder which, in his case, was directly related to two inherited genetic mutations. ECF No. 205 at 10, 15-16. As summarized by the special master, petitioners argued that the vaccinations that Trystan received on February 5, 2009, at the age of six months, "either caused his genetic condition to be expressed or, alternatively, significantly aggravated the course of his disease." Id. at 17. Trystan's symptoms of Leigh's syndrome include "developmental delays[,] . . . dystonia and seizures." Id. at 10.

The special master ruled that petitioners did not establish that Trystan's health "declined in an appropriate temporal window" so as to satisfy "the requirement of establishing but-for causation." <u>Id.</u> at 17 n.12. Petitioners' challenge to the special master's decision is multi-faceted. Some of the criticism levied against the special master could be described as procedural in nature, where petitioners allege that the special master did not employ a fair procedure for the assessment of the evidence before him. Another set of petitioners' arguments focuses more on the special master's conclusions as to the merits of the petition.

The court believes that its review, in these circumstances, must address procedural aspects of the special master's deliberations before turning to the special master's conclusions as to vaccine injury causation. The court reserves its brief discussion of Trystan's relevant medical history, which is controverted, for the causation analysis section of this opinion. First, however, the court addresses the standard of review for the entitlement decisions of special masters in this court's Vaccine Program.

II. Standard of Review

This court has jurisdiction to review the decision of a special master in a Vaccine Act case. 42 U.S.C. § 300aa-12(e)(2). "Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]'" de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008) (quoting 42 U.S.C. § 300aa-12(e)(2)(B) and citing Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005)) (alteration in original). This court uses three distinct standards of review in Vaccine Act cases, depending upon which aspect of a special master's judgment is under scrutiny:

These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard.

Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

The third standard of review, abuse of discretion, is applicable when the special master excludes evidence or otherwise limits the record upon which he relies. See id. As this court has stated, the third standard applies to the special master's evidentiary rulings. Stillwell v. Sec'y of Health & Human Servs., 118 Fed. Cl. 47, 55 (2014) (citation omitted), aff'd, 607 F. App'x 997 (Fed. Cir. 2015). Determinations subject to review for abuse of discretion must be sustained unless "manifestly erroneous." Piscopo v. Sec'y of Health & Human Servs., 66 Fed. Cl. 49, 53 (2005) (citations omitted); see also Milmark Servs., Inc. v. United States, 731 F.2d 855, 860 (Fed. Cir. 1984) (holding that decisions that lie within the trial court's discretion are to be sustained unless "manifestly erroneous") (citation omitted).

III. Analysis

- A. Challenges to Procedural Aspects of the Special Master's Decision-Making
 - 1. The 2009 Day Planner

One of the peculiarities of this case is that Trystan's medical condition was not accurately diagnosed until late 2014, years after the Vaccine Act petition was filed by his parents. ECF No. 205 at 10. By this time, both parties had filed a number of expert reports. See ECF Nos. 47, 52, 54, 65-67, 77. Also by this time, the special master had conducted a one-day evidentiary hearing focusing on events occurring in 2009, from the

time of Trystan's vaccinations, at six months of age, through his one-year check-up. ECF Nos. 28, 33.

As the special master repeatedly delayed a four-day entitlement hearing in this matter due to an ever-evolving evidentiary record, he also ordered the filing of Mrs. Sanchez's "baby journal" and 2009 "day planner." ECF No. 105 at 3 (order). Both Trystan's baby book and Mrs. Sanchez's 2009 day planner were filed on December 12, 2014. ECF No. 107. One of petitioners' arguments is that the day planner, ECF No. 107-6, contained relevant evidence and that the special master did not consider this evidence when he denied their petition. ECF No. 207 at 8; ECF No. 216 at 16.

As respondent observes, however, petitioners failed to point to the significance of the day planner and its contents in their brief filed prior to the four-day entitlement hearing, and failed to elicit any testimony regarding the day planner during that hearing. ECF No. 213 at 22. Two and a half years after the day planner was filed, petitioners' brief did not argue that the day planner supported their entitlement to compensation under the Vaccine Act. See ECF Nos. 107-6, 173. Further, the day planner was not cited in any of the expert reports filed after the day planner was entered into the record of this case, nor was it referenced in expert testimony at the four-day hearing. ECF No. 213 at 22.

Petitioners cannot now argue that the special master ignored their arguments that the day planner contained significant evidence supporting their entitlement to compensation under the Vaccine Act, because no such arguments were made during the phase of this litigation that addressed entitlement. Nor did petitioners introduce the day planner as evidence during the earlier phase of this litigation that addressed events occurring in 2009.² There is no error or abuse of discretion in the special master's consideration of the voluminous evidence in the record of this case, such as the day planner, that was not argued by petitioners to be significant or relevant. Further, even if petitioners had timely relied on the contents of the day planner, the court agrees with respondent, <u>id.</u> at 22-23, that the day planner does not undermine the rationality of the special master's weighing of all of the evidence in this case relevant to Trystan's health in 2009.³

Respondent notes that petitioners did not voluntarily file the day planner, but did so only upon order of the special master, well after the special master had ruled upon the facts relevant to events occurring in 2009. ECF No. 213 at 21-22. Respondent also notes that petitioners did not seek any revision of the special master's fact-finding rulings, issued in 2013, based on the day planner's contents, filed in 2014. Id. at 22.

In their reply brief, petitioners argue, for the first time, that the special master's directives regarding his Ruling Finding Facts, ECF No. 45, discouraged reliance on evidence that might not conform with his fact-finding. ECF No. 216 at 13. To the extent

2. Differences between the Parties' Joint Statement of Facts and the Special Master's Ruling Finding Facts

Petitioners argue that the special master improperly failed to adopt the parties' recitation of the relevant facts occurring in 2009 when he made findings of fact regarding that period of time. In this regard, petitioners state that the special master "disregarded many critical facts" identified by the parties, that these critical facts were "largely ignored," and that this practice led to "discrepancies" between the facts stated by the parties and the facts found by the special master. ECF No. 207 at 7-8. Although the court acknowledges that the special master's directives as to the parties' creation of a joint statement of facts were less than perfectly clear, the court cannot agree with petitioners that the special master's fact-finding as to the events occurring in 2009 was procedurally improper, unfair, arbitrary or capricious, contrary to law, or an abuse of discretion.

After the one-day hearing was held with its focus on events occurring in 2009, the special master directed the parties to each produce "proposed findings of fact," and to exchange these documents.⁴ ECF No. 31 (order). As this process reached fruition, petitioners referenced the upcoming filing of a "(Proposed) Joint Statement of Uncontroverted Facts." ECF No. 39. The special master's next order set a deadline for the filing of the parties" "Proposed Joint Statement of Uncontroverted Facts." ECF No. 40.⁵

that this cursory argument constitutes an attempt to raise an additional ground to set aside the special master's entitlement decision, this argument is untimely raised and waived. See, e.g., Arakaki v. United States, 62 Fed. Cl. 244, 246 n.9 (2004) ("The court will not consider arguments that were presented for the first time in a reply brief or after briefing was complete." (citing Novosteel SA v. United States, 284 F.3d 1261, 1274 (Fed. Cir. 2002); Cubic Def. Sys., Inc. v. United States, 45 Fed. Cl. 450, 467 (1999))).

The written record does not capture the full content of a great number of conference calls that the special master held with the parties. Thus, not every nuance of the instructions given to the parties is available for the court's review. In addition, the special master directed the parties to present any questions to his law clerk and offered a telephone number for this purpose. <u>E.g.</u>, ECF No. 31 at 1. The record does not indicate whether questions were asked of the law clerk, nor does the record memorialize any instructions to the parties provided by the special master's law clerk.

The first occurrence of the terms "Joint" and "Uncontroverted" within the title for the upcoming filing appear in documents drafted and filed by petitioners. <u>Compare ECF Nos. 36, 39, with ECF Nos. 31, 37, 38.</u>

The document was eventually filed. <u>See ECF No. 43</u>. The parties' statement of facts was sometimes referred to as a proposed joint statement of uncontroverted facts, but was also referenced as the parties' joint statement of uncontroverted facts. <u>See ECF Nos. 43</u> at 1; ECF No. 44 at 1-2. Aside from any ambiguities in the title of the document, the status or purpose of the document submitted by the parties for the special master's review is somewhat unclear. The court, for ease of reference, will refer to this document, ECF No. 43, as the parties' Joint Statement of Facts.

The court notes, first, the absence of the term "stipulation" in the title of the document. The court cannot agree with petitioners' view that this document constituted, in effect, a Joint Stipulation of Facts. See ECF No. 207 at 7 & n.1 (using the term "Stipulated Facts" to describe the parties' Joint Statement of Facts, and discussing "stipulations" as an example of a judicial admission); ECF No. 216 at 5-6 (contending that the parties had stipulated to certain facts in their Joint Statement of Facts). As respondent points out, many of the facts submitted in the Joint Statement of Facts are controverted by respondent through the Secretary's commentary in the footnotes of this document, which address the lack of documentary evidence that might support certain "proposed facts." ECF No. 213 at 8 n.4. The court notes that of the 36 paragraphs of factual allegations in the parties' Joint Statement of Facts, 12 contain one or two footnotes explaining why respondent did not support the inclusion of certain statements of fact as proposed, relevant facts. See ECF No. 43 at 2-8, 11-12. Whatever the purpose of the document jointly filed by the parties, the court does not consider it to be a joint stipulation of facts.

Petitioners argue that the special master "disregarded" or "ignored" certain pronouncements in the parties' Joint Statement of Facts when he issued his Ruling Finding Facts on April 10, 2013, and his entitlement decision on October 9, 2018. ECF No. 207 at 7, 21, 43. In their view, the special master's practice evidenced "predisposed fact-finding." <u>Id.</u> at 22. In their reply brief, petitioners state that the special master "changed the facts." ECF No. 216 at 6. In addition, petitioners argue that the special master inserted controversy, in some instances, where there was none. Id. at 7.

As petitioners acknowledge, the special master incorporated <u>some</u> of the parties' Joint Statement of Facts into his Ruling Finding Facts. <u>Id.</u> at 6 n.1. The crux of their challenge to the special master's Ruling Finding Facts, ECF No. 45, is that some of his fact-finding does not give credence to representations of fact that are present either in the parties' Joint Statement of Facts or in Mrs. Sanchez's 2009 day planner. ECF No. 207 at 10-13.

The court has reviewed both the parties' Joint Statement of Facts and the special master's Ruling Finding Facts. The differences between these two recitations of fact largely reflect the special master's greater reliance on contemporaneous medical records

and <u>lesser</u> reliance on the testimony provided by Sanchez family members.⁶ This type of weighing of the evidence is sanctioned by binding precedent cited by the special master. ECF No. 45 at 3 (citing <u>Cucuras v. Sec'y of Dep't of Health & Human Servs.</u>, 993 F.2d 1525, 1528 (Fed. Cir. 1993)). Because the special master's Ruling Finding Facts is neither arbitrary nor capricious in its content, and is not procedurally infirm, petitioners' motion for review cannot succeed on this ground.⁷

The court observes, however, that the special master's request for proposed findings of facts from the parties, and his directive that a Proposed Joint Statement of Uncontroverted Facts be filed, might mislead the parties in a future Vaccine Act case into an attempt to produce a Joint Stipulation of Facts to which the parties would be bound. Petitioners here cite caselaw that calls into question a court's fact-finding that does not adopt stipulated facts filed by the parties in a case before that court. See ECF No. 216 at 7-9 (citing authorities). If the special master intends to issue fact-findings that may not adopt separately filed proposed findings of fact, and which also may not adopt jointly filed proposed findings of fact, that intention is best communicated to the parties through written orders in the record.

B. Challenges to the Special Master's Causation Analysis

Petitioners attack the special master's causation analysis on a number of fronts. The court discerns five principal allegations of error in the motion for review, which are addressed below.⁸ The court notes, however, that many of petitioners' arguments about

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The special master also noted that the mere citation of witness testimony was unhelpful because it did not address "the truth of the underlying assertion" of fact. ECF No. 45 at 2 n.1 (citing ECF No. 43 at 6).

Petitioners also allege that the special master was not always consistent in his fact-finding regarding the events that occurred in 2009, when his Ruling Finding Facts is compared to his entitlement decision. See ECF No. 216 at 6-7. The court finds that the differences between the fact-finding in these two documents do not undermine the entitlement decision's analysis or conclusions. The differences reflect an evolution in the special master's understanding of the factual backdrop of this case. See infra.

The court does not address a number of minor criticisms of the special master's causation analysis in petitioners' lengthy motion for review. As the Federal Circuit has held, when "the special master's conclusion was based on evidence in the record that was not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious." Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1363 (Fed. Cir. 2000). The court has considered all of petitioners' arguments, but this special master's entitlement decision cannot be disturbed under the deferential standard of review applicable here.

causation present the undersigned with an invitation to reweigh the evidence before the special master. This reviewing court "does not reweigh the factual evidence or assess whether the special master correctly evaluated the evidence, nor does it examine the probative value of the evidence." <u>Porter v. Sec'y of Health & Human Servs.</u>, 663 F.3d 1242, 1254 (Fed. Cir. 2011). Instead, the court must defer to the fact-finding role of the special master.

For general guidance, the court cites here a few of the pertinent facts found by the special master in his entitlement decision. Some of these facts are disputed by petitioners, but the special master's fact-finding provides a necessary framework for the causation analysis reviewed here. The focus of petitioners' disagreement with the special master's fact-finding is on the six-month period after Trystan received vaccinations on February 5, 2009.

Trystan had an adverse reaction to the vaccinations, including fever. ECF No. 205 at 3. Over the next few months, he had colds, but was "neurologically normal." <u>Id.</u> By the beginning of May 2009, at the earliest, "Trystan first started showing signs of loss of skills." <u>Id.</u> at 8. Neurological problems were detected at a doctor's visit on October 7, 2009. <u>Id.</u> at 9. It was not until late 2014 that Trystan was diagnosed with Leigh's syndrome. Id. at 10.

The court turns now to petitioners' allegations of error in the special master's causation analysis.⁹

1. Challenge-Rechallenge Theory of Causation

Petitioners point to an alleged error in the special master's causation analysis, complaining that it "is oddly silent on the issue of challenge-rechallenge." ECF No. 207 at 38. In petitioners' view, the special master "disregard[ed] the evidence of 'challenge-rechallenge.'" <u>Id.</u> Petitioners argue that this portion of their theory of causation, which focused on a second set of vaccinations given to Trystan on August 17, 2009, was "fully briefed," was the subject of expert reports and expert testimony, and was supported by notations in Trystan's medical records. ¹⁰ <u>Id.</u> at 38-42. Because petitioners allege that the

Previously addressed allegations of error, such as petitioners' criticism of the differences between the special master's Ruling Finding Facts and the parties' Joint Statement of Facts, will not be addressed again here. That procedural aspect of the case, the court recognizes, is inextricably bound up with the entitlement decision's causation analysis. The Ruling Finding Facts was not erroneous, either as the procedural follow-up to the one-day hearing and the parties' Joint Statement of Facts, or as an example of the special master's weighing of the evidence before him.

Fully briefed may not be an apt description. The challenge-rechallenge section of petitioners' pre-hearing brief is not identified as such in the table of contents, and

special master's fact-finding as to the evidence of challenge-rechallenge was flawed, their burden is to show that the omission of any discussion of the challenge-rechallenge aspect of their theory of causation was arbitrary or capricious. Munn, 970 F.2d at 870 n.10.

The court has reviewed both the special master's entitlement decision, ECF No. 205, and his Ruling Finding Facts, ECF No. 45. The entitlement decision is clearly founded on the findings of fact issued by the special master five years earlier. See ECF No. 205 at 6 (stating that the Ruling Finding Facts would be "briefly reviewed" in the entitlement decision); id. at 7-8 (citing six pages of the Ruling Finding Facts); id. at 11 (again mentioning the Ruling Finding Facts). The Ruling Finding Facts shows that the special master considered evidence of adverse symptoms related to Trystan's second set of vaccinations, but considered them to be less persuasive than contemporaneous medical records. See ECF No. 45 at 15 n.11. Because the special master weighed the relevant evidence of rechallenge symptoms, and found the evidence to be unpersuasive, it was not error for the special master to also find petitioners' expert testimony as to rechallenge to be so unpersuasive as to be unworthy of mention in his entitlement decision. See ECF No. 205 at 11 n.7 (noting that the special master had considered all expert reports, although his decision could not discuss each of the many expert reports filed in this case).

There is no indication that the special master ignored any significant evidence provided by petitioners. Even though the specific facet of petitioners' causation theory that relied on rechallenge symptoms occurring after Trystan's second set of vaccinations was not mentioned by the special master, he had already found that such symptoms probably did not occur. For this reason, the causation analysis in the entitlement decision has not been shown to be arbitrary or capricious. See Milik v. Sec'y of Health & Human Servs., 822 F.3d 1367, 1382 (Fed. Cir. 2016) (affirming a special master's denial of compensation in a Vaccine Act case because "the special master thoroughly reviewed all of the relevant evidence, including the expert witnesses' testimonies and reports").

2. Evidence of Neurodegeneration

Petitioners argue that the evidence of Trystan's neurodegeneration in 2009, as interpreted by their experts, shows that Trystan's vaccine-related injury occurred within

occupies only 3 pages in a narrative of approximately 60 pages. <u>See ECF No. 173 at 44-46.</u>

As this court has held, a special master's written decision, created pursuant to the streamlined procedures of the Vaccine Program, need not address "every argument" raised by a party. <u>Doe/17 v. Sec'y of Health & Human Servs.</u>, 84 Fed. Cl. 691, 704 n.18 (2008) (citing <u>Bradley v. Sec'y of Dep't of Health & Human Servs.</u>, 991 F.2d 1570, 1576 (Fed. Cir. 1993)).

an acceptable time frame. ECF No. 207 at 32-34. Respondent contends that the record evidence of neurodegeneration does not support an earlier date of disease onset than the date of onset found by the special master. ECF No. 213 at 23-25. The court declines petitioners' invitation to reweigh the evidence as to disease onset. See Porter, 663 F.3d at 1254 (noting that the reviewing court does not reweigh the evidence of record). Nothing in the allegations of fact or expert opinions cited by petitioners shows that the special master's findings as to disease onset were arbitrary or capricious.

3. Precedential Guidance in Paluck II

Petitioners extensively rely on Paluck v. Sec'y of Health & Human Servs., 786 F.3d 1373 (Fed. Cir. 2015) (Paluck II), and the underlying decision from this court, Paluck v. Sec'y of Health & Human Servs., 113 Fed. Cl. 210 (2013) (Paluck I), aff'd, 786 F.3d 1373 (Fed. Cir. 2015), for two related but distinct arguments. Petitioners' first argument is that the Federal Circuit's analysis of relevant scientific articles, and the appeals court's conclusions about the timing of the onset of mitochondrial diseases, are binding in this case. See ECF No. 207 at 29 (citing Paluck II, 786 F.3d at 1383-84). 12 Petitioners' second, broader argument is that the special master in this case adopted an analytical approach for Althen Prongs II and III that was specifically rejected in Paluck II. 13 See id. at 30 (citing Paluck II, 786 F.3d at 1382-84). Neither of these arguments is persuasive.

The court turns first to the question of whether Paluck II dictates a finding of entitlement to Vaccine Act compensation in this case. It does not. As respondent makes clear, there are evidentiary differences between the record in this case and the record discussed in Paluck II. ECF No. 213 at 25-26. The Federal Circuit has held that where evidentiary records are "significantly different," the causation analyses in Vaccine Act cases may be different, and may produce different results. See Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1325 (Fed. Cir. 2010) (noting that the causation proved in Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367 (Fed. Cir. 2009), did not compel a finding of causation in Moberly). Applying the precedent in Moberly to this case, petitioners have not shown that the evidentiary

¹² Petitioners incorrectly cite to pages 1390 and 1391 of the reporter; the relevant section of Paluck II is found on pages 1383 and 1384.

¹³ The Althen Prong II might be succinctly described as the question of whether the vaccine was the "reason" for this illness in this child, and the Althen Prong III might be described as the question of whether the onset of the symptoms of the illness occurred within an appropriate time frame after the vaccination. Althen, 418 F.3d at 1278; see also Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

record in this case is so similar to that of <u>Paluck II</u> that the special master was compelled to find that Trystan's vaccinations caused or significantly aggravated his health problems.

Turning to petitioners' second argument, they argue that the special master's approach to <u>Althen Prongs II</u> and III in his entitlement decision was specifically rejected in <u>Paluck II</u>. The court cannot agree. First, the court observes that the Federal Circuit in <u>Paluck II</u> rejected an entitlement decision because the special master's decision contained many flaws:

Where, as here, a special master misapprehends a petitioner's theory of causation, misconstrues his medical records, and makes factual inferences wholly unsupported by the record, the Court of Federal Claims is not only authorized, but obliged, to set aside the special master's findings of fact and conclusions of law.

<u>Paluck II</u>, 786 F.3d at 1380. The rejection of the special master's causation analysis in <u>Paluck II</u> was based on a number of flaws not present here.

The court has reviewed the analysis before it and does not find that the special master, here, misunderstood the theories of causation presented by petitioners. Nor does the court find that the special master misconstrued Trystan's medical records. Finally, the court cannot conclude that the special master's fact-finding was "wholly unsupported by the record." Paluck II, 786 F.3d at 1380. For these reasons, the special master's entitlement decision, as a whole, is unlike the decision rejected by the Federal Circuit in Paluck II, and cannot be reversed simply because there are some similarities between the analytical framework utilized in these two Vaccine Act cases.

As for the <u>Althen Prong III</u> analysis in these two cases, they are not exactly the same. In <u>Paluck II</u>, the special master defined the appropriate time frame for the onset of symptoms to be within twenty-one days. 786 F.3d at 1383-84. Given the evidence before the special master in that case, the Federal Circuit held that he had no "reasonable basis" for choosing twenty-one days as the limit for the appropriate time frame, or that twenty-three days would be too late to fall within the appropriate time frame. <u>Id.</u> Here, as respondent points out, there was an entirely different evidentiary record, and the special master did not state that the appropriate time frame window closed twenty-one days after vaccination. ECF No. 213 at 25-26.

Petitioners acknowledge that the special master, here, did not state that he had established a hard and fast deadline for the appearance of symptoms, so as to satisfy Althen Prong III. ECF No. 207 at 29 (citing ECF No. 205 at 26). Indeed, the special master relied, instead, on the principle that "as the post-vaccination interval extends beyond two weeks, the likelihood that the [decline in health] is attributable to a reaction to the vaccine, as opposed to another cause, drops." ECF No. 205 at 26 (citing Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1358 (Fed. Cir. 2006)). Because the

special master did not use the temporal measure that was faulted in <u>Paluck II</u>, the decision in <u>Paluck II</u> does not compel a finding here that the special master employed an inappropriate Althen Prong III analysis.

Finally, petitioners argue that their expert testimony conforms with the type of proof that was accepted for <u>Althen</u> Prong III in <u>Paluck II</u>. ECF No. 207 at 30-31. The court need not decide whether the expert testimony cited by petitioners is analogous to the expert testimony in the record discussed in <u>Paluck II</u>. The special master here was obliged to consider <u>all</u> of the evidence before him and to weigh that evidence. <u>See, e.g., Moriarty by Moriarty v. Sec'y of Health & Human Servs.</u>, 844 F.3d 1322, 1330 (Fed. Cir. 2016) (stating that the Vaccine Act "requires the special master to consider all relevant medical and scientific evidence of record"). The special master found that two of petitioners' experts relied on factual assumptions that were inconsistent with Trystan's medical records. ECF No. 205 at 23 n.17. In his role as fact-finder, the special master concluded that the expert opinions as to neurodegeneration relied upon by petitioners were unpersuasive. <u>Id.</u> Although some of the evidence in this case may be reminiscent of the evidence discussed in <u>Paluck II</u>, the court sees no error in the special master's weighing of the evidence in this case.¹⁴

4. Petitioners' Analysis of Colds and Infections Criticized

Petitioners also argue that the special master incorrectly found their expert testimony to be inadequate on the topic of the possible impact of Trystan's colds and other infections on his decline in health. ECF No. 207 at 37-38 (citing ECF No. 205 at 28 & n.20). That section of the entitlement opinion states that petitioners' "inability, or failure, to address a conspicuous and probable alternate cause for the manifestation of Trystan's Leigh's syndrome weighs against a finding that the vaccination caused Trystan's injury." ECF No. 205 at 28. It may be that the terms "inability" and "failure" are somewhat harsh, but it is clear that the special master viewed the arguments presented by petitioners on this topic to be inconsequential and inadequately persuasive.

Petitioners cite to the record to show that their experts <u>did</u> discuss colds and infections to some extent. ECF No. 207 at 38. The court does not find, however, that the special master's characterization of this testimony as a "failure[] to address" alternative causation was arbitrary or capricious. ECF No. 205 at 28. Further, even if the special master had erred in his weighing of the expert testimony as to alternative causation, a proposition with which the court cannot agree, he specifically stated that his entitlement

Similarly, the court cannot reweigh the evidence which petitioners cite in an effort to establish a longer temporal window for the <u>Althen Prong III</u> analysis required in this case. <u>See ECF No. 207 at 30 n.30</u> (stating that their expert posited that 2-3 months was an appropriate window for neurodegeneration after vaccination); ECF No. 216 at 16 (same).

decision did <u>not</u> depend on the evidence of alternative causation, but on an "independent" assessment of petitioners' evidence of causation. <u>Id.</u> at 28 n.20. Therefore, the error alleged by petitioners here would be a harmless error, in any case, because the special master's causation analysis, which focused on <u>Althen</u> Prongs II and III, has not been shown to be erroneous.

5. Arm Contortions as a Cold Symptom

Petitioners' final challenge to the special master's entitlement ruling focuses on his characterization of Trystan's arm contortions on or about February 15, 2009, as being typical of "an infant suffering from a cold." ECF No. 205 at 7. According to petitioners, the evidence before the special master "does <u>not</u> remotely indicate that the arm contortions were consistent with a cold." ECF No. 207 at 25. The special master's assessment of the evidence of Trystan's health from February 15-17, 2009, did evolve over time, but his fact-finding in this regard rationally supports the causation analysis presented in the entitlement decision.

The backdrop for the special master's recitation of facts is the presence of two types of information in the record--that provided by Trystan's family, and that provided by contemporaneous medical records. As noted earlier in this opinion, the special master favored the written records preserved by Trystan's medical providers over oral testimony or written allegations provided later by the Sanchez family. See, e.g., Ruling Finding Facts, ECF No. 45 at 3-5, 8-10. The court notes that the events of February 15-17, 2009, were established by a combination of these two types of evidence.

There is no dispute that February 15, 2009, was Mrs. Sanchez's birthday. As noted in the parties' Joint Statement of Facts, Trystan fell ill beginning on that day. ECF No. 43 at 4. He continued to be ill the next day, February 16, 2009. <u>Id.</u> at 4-5. Trystan was brought to a pediatrician on February 17, 2009, where he was diagnosed with a common cold and viral syndrome. <u>Id.</u> at 5. The parties disputed the evidence as to what symptoms were reported at the pediatrician's office. <u>Id.</u> at 5 n.4.

In his Ruling Finding Facts, the special master made a number of findings regarding these three days, and Trystan's health in the next few months. The special master found that on February 15, 2009, Trystan had a fever and was congested. ECF No. 45 at 12. During the night of February 16, 2009, Trystan had a worsening fever, a stuffy nose, and was "jerking around" in his father's arms. <u>Id.</u> On the morning of February 17, 2009, Trystan was diagnosed at the pediatrician's office with a cold and viral syndrome, and Mrs. Sanchez reported that Trystan had been "coughing, congested, [and] with fever." <u>Id.</u> at 13.

Most significantly, the special master's review of the evidence, including the parents' allegations of fact, determined that no report of "unusual arm movements" was given to the medical staff on February 17, 2009, and that Trystan was not having arm

contortions at this time. <u>Id.</u> The special master also found that no reports of arm contortions were given to a medical provider on April 29, 2009, and that no arm contortions had occurred between February 15, 2009 and April 29, 2009. <u>Id.</u> In his interim fees decision issued almost three years later, which cited his Ruling Finding Facts, the special master summarized his findings regarding Trystan's arm contortions and stated that these did not begin until August 2009. ECF No. 135 at 8 (citing ECF No. 45 at 13-15).

In his entitlement decision, however, there is a revised recitation of facts pertaining to cold symptoms and arm movements occurring during those three days in February 2009, in a section which "briefly reviewed" his Ruling Findings Facts. ECF No. 205 at 6. On one hand, the special master, diverging from his Ruling Finding Facts, notes that Trystan's "arms contorted and he was jerking around" on or about February 15, 2009. Id. at 7. On the other hand, as in the Ruling Finding Facts, the special master asserts that only cold symptoms, not neurological symptoms, were either reported to or observed by the medical staff at the pediatrician's office on February 17, 2009. Id. Again, as in the Ruling Finding Facts, the special master found that no neurological symptoms occurred between February 17, 2009 and April 29, 2009, and that no reports of neurological symptoms, as opposed to cold symptoms, were reported to the doctor consulted on the latter date. Id. at 8.

The differences between the special master's Ruling Finding Facts and his entitlement decision's recitation of facts are not explained. ¹⁵ It appears that the special master was, over time, more receptive to the parents' testimony as to arm contortions occurring in mid-February 2009 by the time he wrote the entitlement decision, but wished to specify that these manifestations were consistent with cold symptoms, not neurological problems. Thus, where arm contortions in February 2009 were found not to have occurred, in the Ruling Finding Facts, they are specifically mentioned in the entitlement decision as having occurred in February 2009.

In his entitlement decision, despite the occurrence of arm contortions in February 2009, the special master concluded that no neurological symptoms were experienced in February, March and April 2009, because no such symptoms had been reported by Trystan's parents to treating physicians or other medical professionals in this time period. ECF No. 205 at 7-8. Further, based on his reading of all of the evidence, the special master revised his finding of fact regarding the onset of symptoms of Leigh's syndrome, stating that these occurred at the beginning of May 2009, at the earliest. Id. at 8 & n.3. The relatively minor adjustments to the special master's recitation of facts, over the

In another instance, the entitlement decision explains why a finding of fact was changed from the finding on the same issue in the Ruling Finding Facts. See ECF No. 205 at 8 & n.3 (changing the onset of symptoms from a possible range of May 17, 2009 through June 17, 2009, to the beginning of May 2009, at the earliest).

course of several years of litigation, are not irrational or arbitrary, in the court's view. Despite these two revisions to his understanding of Trystan's health in the first half of 2009, the special master consistently derived reasonable inferences from the record before him

As for petitioners' contention that the special master could not have found that Trystan's arm contortions in February 2009 should be attributed to cold symptoms, as opposed to neurological symptoms, the record, instead, plausibly supports the special master's finding. As respondent points out, the cold and viral syndrome diagnosis for Trystan's illness during this time period is documented in Trystan's medical records. ECF No. 213 at 20. As respondent argues, the special master derived "plausible inferences" from these medical records, and testimony provided at the four-day entitlement hearing, to conclude that the arm contortions exhibited by Trystan in mid-February 2009 were consistent with cold symptoms, and not indicative of neurological symptoms. Id. at 21.

In their reply brief, petitioners argue that nothing in the hearing transcript pages cited by respondent could support the special master's finding that Trystan's arm contortions were mere cold symptoms. ECF No. 216 at 12. Indeed, petitioners characterize the special master's fact-finding in this regard as an "impermissible inference." <u>Id.</u> The transcript pages cited by the parties are indeed relevant to this dispute.

An expert in pediatrics and pediatric immunology testified at the four-day entitlement hearing. ECF No. 201 at 41-42 (transcript). The following exchange occurred:

- Q. Do you believe the fever Trystan had eleven days after his February 5th, 2009 vaccination was a reaction to the vaccine?
- A. I do not.
- Q. And why is that?
- A. Well, the [vaccine] reaction . . . would not be expected to persist for that long, and there is nothing in the record that I could find, either from the testimony of the Sanchez family or anything from the medical record itself, that would suggest that it was other than a separate event.

Added to that is the findings, both the description of the family of what symptoms the boy had, and the findings of Mr. Luna [at the pediatrician's office] when they sought medical care on the 17th of February, were consistent with an upper respiratory infection.

ECF No. 201 at 44-45. Because respondent's expert testified that the symptoms described by the Sanchez family, which according to their testimony included arm contortions, were consistent with an upper respiratory infection, it was not an impermissible inference for the special master to conclude that any arm contortions exhibited by Trystan in mid-February 2009 should be characterized as cold symptoms, not neurological symptoms.

There was further testimony from another expert who specifically addressed the question of neurological symptomology before June 1, 2009, who stated that Trystan "was seen several times by practitioners [between February 5, 2009 and June 1, 2009], and there was no comment at all on neurologic issues." <u>Id.</u> at 144. This expert also testified that he did not believe that Trystan had a seizure during the February 15-17, 2009 time period, because his symptoms at the time were evidence of "startling awake with a cold." <u>Id.</u> at 143-44. The expert testimony cited by respondent supports the special master's finding that no neurological symptoms occurred in February, March and April 2009. Although petitioners and their experts have a different view of the significance of arm contortions in mid-February 2009, the special master's findings in this regard are reasonably supported by expert testimony and other evidence in the record. The court must defer to the fact-finding role of the special master and cannot reconsider the expert opinions and other evidence cited by petitioners. <u>See Porter</u>, 663 F.3d at 1254 (noting that the reviewing court does not reweigh the evidence of record).

IV. Conclusion

For the above-stated reasons, the court sustains the entitlement decision of the special master. Accordingly, it is hereby **ORDERED** that:

- (1) Petitioners' motion for review, ECF No. 207, is **DENIED**;
- (2) The decision of the special master, filed October 9, 2018, is **SUSTAINED**;
- (3) The clerk's office is directed to **ENTER** final judgment in accordance with the special master's decision of October 9, 2018; and,
- (4) The parties shall separately **FILE** any proposed redactions to this opinion, with the text to be redacted clearly blacked out, on or before **February 25**, **2019**.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
PATRICIA E. CAMPBELL-SMITH Judge